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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/049,227	03/27/1998	MARTIN P. REDMON	4821-304	5249

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	27

DATE MAILED: 09/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/049,227	REDMON ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2002 and 03 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

I. The request filed on Aug. 2, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/049,227 is acceptable and a CPA has been established. An action on the CPA follows.

The following is responsive to the amendment received Jan. 3, 2002.

Applicant's arguments with respect to claims 1-37 have been considered but are moot in view of the new ground(s) of rejection.

Status of the Claims

No new claims are added. No claims are cancelled.

Claims 1-37 are currently pending.

Claim Rejections - 35 USC § 102

II. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

III. Claims 21, 29 are rejected under 35 U.S.C. 102(e) as being anticipated by El-Rashidy et al., 5,830,500.

El-Rashidy et al. disclose the invention substantially as claimed. Specifically, El-Rashidy et al. teach a compressed tablet comprising racemic fluoxetine hydrochloride, a lubricant and a disintegrant such as microcrystalline cellulose or pregelatinized

starches. A preferred compressed tablet formulation is described in TABLE 1. Please see col. 2, lines 8-9 and lines 52-55; col. 3, lines 37-43; TABLE 1.

Claim Rejections - 35 USC § 103

IV. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

V. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

VI. Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over El-Rashidy et al., supra in view of Young et al., 5,104,899 and Young et al., 5,648,396 and WO 97/28788 ('788) (submitted by Applicant).

In addition to the teachings described above, El-Rashidy et al. further disclose that the compositions are made from dry ingredients and formed into tablets by direct compression method. Please see col. 3, lines 64-66. Moreover, while the claimed tablets dissolve in less than three minutes, El-Rashidy does disclose that commercially known fluoxetine compositions dissolve in 4 minutes 36 seconds. See col. 5, lines 61-64. Finally, the preferred compositions of El-Rashidy do not contain lactose. Please see Table 1.

El-Rashidy et al. do not disclose pharmaceutical compositions containing an optically pure enantiomer of fluoxetine, nor does El-Rashidy teach that the fluoxetine containing pharmaceutical compositions are used for treating depression; however, the Examiner refers to **(1)** Young et al., '899, which disclose methods and compositions for treating depression, the methods comprising administering oral compositions containing effective amounts (5-100mg) of pure S(+) isomer of fluoxetine. The compositions may be in the form of capsules or tablets and are formulated according to standard techniques. Please see the abstract; col. 3, lines 49-56; col. 6, lines 32-34 and lines 64-68; col. 7, lines 19-64; and **(2)** Young et al., '396 which disclose methods for treating depression by administering compositions containing effective amounts (1-100mg) of optically pure R(-) fluoxetine. The compositions may be in the form of capsules or tablets and are formulated according to standard techniques. Please see the abstract; col. 6, lines 13-19; col. 10, line 25 to col. 11, line 22.

It would have been obvious to one of ordinary skill in the art to modify the pharmaceutical compositions of El-Rashidy et al. to contain optically pure enantiomers of fluoxetine and to use such compositions for treating depression because both Young et al., '396 and '899 disclose that the R- and S- enantiomers of fluoxetine have potent antidepressant activity (please see the abstracts). Thus, such a modification would have been motivated by the reasoned expectation of successfully producing a pharmaceutical composition which is effective in treating patients suffering from depression. In other words, one of ordinary skill in the art would reasonably expect either enantiomer to have effective antidepressant activity.

Concerning the claimed dissolution times of not less than three minutes or more than five minutes, it is submitted that in view of El-Rashidy's disclosure, dissolution time is an art-recognized result-effective variable and it would have been obvious and well within the capability of the skilled artisan to optimize it the compositions of El-Rashidy. The Examiner additionally relies on WO '788, which discloses that dissolution time is one of several known physical characteristics of a tablet (page 3, last three lines). The harder a tablet is the more time it takes to dissolve (page 4, first full paragraph). Absent evidence to the contrary, it would be obvious to one of ordinary skill in the art to modify the components of a composition until a desired dissolution time, i.e. "not less than three minutes" or "more than five minutes", is acquired. For example, the lack of a disintegrant would obviously result in a composition that does not dissolve as quickly as it would with a disintegrant.

With respect to the claimed compositions being anhydrous or nonhygroscopic or substantially free of unbound water, the Examiner submits that this is obvious in view of El-Rashidy's teaching that the compressed tablets are made from dry ingredients. Moreover, it is noted that the specification at page 15, lines 27-33 defines "anhydrous"

as substantially free of unbound water or the amount of unbound water (if present) is insufficient to accelerate incompatibility between fluoxetine and lactose. Applicant has argues that El-Rashidy disclose a fluoxetine composition containing an ingredient, dicalcium phosphate dihydrate, which contains water . Therefore, the disclosed compositions cannot be anhydrous. However, the Examiner respectfully submits that the term "anhydrous" as defined does not exclude all water (substantially free of water) and further that the water molecules appear to be bound to the dicalcium phosphate and therefore would not be expected to detrimentally affect the overall composition since, as the specification states, it is the presence of unbound water which is undesirable. The Examiner respectfully maintains that El-Rashidy discloses a dry fabrication process and that one of ordinary skill in the art would reasonably expect the ultimate fluoxetine compositions to be essentially free of water. Finally, both Young et al., '899 and '396 disclose examples of capsule compositions where water is not required. Please see Example 2 in the '899 patent and Example 6 in the '396 patent.

Finally, in addressing claim 14, which require specific amounts by weight of fluoxetine and excipient, concentration limitations are obvious absent evidence to the contrary. Please see Akzo v. E.I. du Pont de Nemours, 1 USPQ 2d 1704 (Fed. Cir. 1987).

Conclusion

Claims 1-37 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **(703) 306-3227**. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Marianne Seidel**, can be reached on **(703) 308-4725**. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the **Group receptionist** whose telephone number is **(703) 308-0196**.

CDM
Sep. 20, 2002

Cybille Delacroix-Muirheid
Patent Examiner Group 1600